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UNITED STATES DISTRICTOCOURT DISTRICT OF MASSACHUSETTS 2013 APR -8 P 12: 27	
UNITED STATES OF AMERICA)	U.S. DIETIMINAUNO. 136/098
v. ,	VIOLATIONS: 18 U.S.C. § 1347 - Health Care Fraud 42 U.S.C. §1320a-7b - Kickbacks
HUNTER RIGSBY)	o de la companya de l

INFORMATION

The United States Attorney charges that:

BACKGROUND

- 1. The defendant **HUNTER RIGSBY** ("RIGSBY"), a resident of Tennessee, was an employee of Orthofix, Inc. ("Orthofix").
- 2. Orthofix, a Minnesota corporation with a principal place of business in Lewisville, Texas, manufactured and distributed in interstate commerce bone growth stimulator medical devices. Bone growth stimulators were externally-worn devices that emitted pulsed electromagnetic fields and stimulated regeneration of bone cells at the site of an injured bone. Orthofix sold two types of bone growth stimulators: (1) the Physio-Stim, which was used to treat certain bones that had suffered fractures and had not healed properly; and (2) the Cervical-Stim and Spinal-Stim, which were used to aid the healing of spinal fusions.
- 3. **RIGSBY** was an Orthofix Territory Manager covering portions of Tennessee, including Knoxville, from 2005-09. At various times, **RIGSBY** sold the Physio-Stim, Cervical-Stim, and Spinal-Stim. After he was separated from Orthofix, **RIGSBY** continued to sell these products until at least 2011.

- 4. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care for persons aged 65 and older, and for persons with disabilities. The funds set aside by Congress to pay for the necessary medical care of these elderly Americans, and any premiums paid by such persons, were referred to as the Medicare Program Trust Funds.
- 5. The Center for Medicare & Medicaid Services ("CMS") was a federal agency within the U.S. Department of Health and Human Services ("HHS") that was responsible for the funding, administration and supervision of the Medicare Program.
- 6. Pursuant to sections 1832(a)(1) and 1861(n) of the Social Security Act, Medicare Part B provided for the coverage of certain durable medical equipment ("DME"). CMS contracted with four Medicare Administrative Contractors to process and pay Medicare Part B claims for DME.
- 7. Orthofix was an accredited DME supplier enrolled in the Medicare program. As an accredited supplier, Orthofix was authorized to submit directly to Medicare contractors claims for reimbursement for bone growth stimulators provided to Medicare Program beneficiaries.
- 8. To obtain payment from Medicare for a bone growth stimulator prescribed by a physician, CMS required Orthofix to obtain and maintain, among other records, medical records describing the patient's injury or condition. CMS also required Orthofix to submit a Certificate of Medical Necessity ("CMN") and a prescription.
- 9. For DME that was covered by Medicare, Medicare suppliers were reimbursed the lower of the actual fee for the item or the fee that Medicare approved for the item. The Medicare-

approved amount for reimbursement of the Orthofix bone growth stimulators varied over time, ranging from approximately \$3,500 to more than \$4,400 for each device.

- 10. Medicare published guidelines establishing when bone growth stimulators were covered for beneficiaries. **RIGSBY** was familiar with these guidelines, which were widely disseminated at Orthofix.
- 11. With respect to long bone stimulators such as the Physio-Stim, Medicare only covered this device if any the following criteria were met:
 - (1) Nonunion of a long bone fracture, defined as radiographic evidence that fracture healing had ceased for three or more months prior to starting treatment with the osteogenesis stimulator; or
 - (2) Failed fusion of a joint other than in the spine where a minimum of nine months had elapsed since the last surgery; or
 - (3) Congenital pseudarthrosis.
- 12. As **RIGSBY** knew and understood, Medicare would not pay for a Physio-Stim without the required "a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs."
- 13. With respect to spinal stimulators such as the Cervical-Stim and Spinal-Stim, Medicare only covered these devices if any of the following criteria were met:
 - (1) Failed spinal fusion where a minimum of nine months had elapsed since the last surgery; or
 - (2) Following a multilevel spinal fusion surgery; or
 - (3) Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.
- 14. Several private insurance carriers in **RIGSBY's** sales territory also followed Medicare's guidelines for bone growth stimulators.

- 15. When a physician prescribed an Orthofix bone growth stimulator, an Orthofix Territory Manager collected the medical records and prescription from the physician and forwarded these documents to an Insurance Administrator at Orthofix's home office. The Insurance Administrator prepared and submitted the claim to the applicable insurance carrier.
- 16. As **RIGSBY** knew and understood, the law prohibited, among other things, the offer or payment of remuneration to physicians or their staff to induce the order of items or services for which payment would be made, in whole or in part, under the Medicare program, conduct often referred to as "kickbacks" or "bribes."

COUNT 1 18 U.S.C. §1347 (Health Care Fraud)

- 17. The allegations in paragraphs one through 16 are herein realleged and incorporated in full.
- 18. From 2005 to in or about 2011, in the Eastern District of Tennessee and elsewhere, the defendant

HUNTER RIGSBY

did knowingly and willfully execute a scheme and artifice to defraud Medicare, a health care benefit program, in connection with the delivery of and payment for health care benefits, items and services, and to obtain, by means of false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, Medicare, in violation of Title 18, United States Code, Sections 1347 and 2, as set forth below.

RIGSBY Submitted Claims Where A Physician Did Not Prescribe a Stimulator

- 19. On several occasions, **RIGSBY** submitted orders to Orthofix even though no physician had ordered a stimulator for the patient.
- 20. For instance, in June 2006, **RIGSBY** submitted an order for a Physio-Stim for patient JB. The paperwork **RIGSBY** submitted indicated that JB had sustained an injury and had been treated by Dr. CT. **RIGSBY** also submitted a form with JB's purported signature indicating that JB received the device and authorized Orthofix to bill on JB's behalf. In fact, JB did not have an injury requiring a bone growth stimulator in June 2006 or at any other time. JB never received a bone growth stimulator, and he did not sign the form that **RIGSBY** submitted.
- 21. As another example, in December 2008 **RIGSBY** submitted an order for a Physio-Stim for patient EG. **RIGSBY** submitted purported medical records, including chart

notes from physician Dr. ML, describing the patient's alleged tibia fracture. **RIGSBY** also submitted a CMN and a prescription bearing Dr. ML's signature. In fact, Dr. ML never treated this patient. **RIGSBY** falsified the chart notes, CMN and prescription to induce Medicare to pay this claim. Medicare paid Orthofix \$2,662.93 and a secondary insurer paid \$665.73 for this claim.

22. As another example, in May 2008, Dr. ML performed spinal fusion surgery on patient BG. RIGSBY submitted an order for a Physio-Stim—the device that treats long bones such as arms, legs, fingers and toes—for BG for a purported forearm fracture. RIGSBY submitted purported medical records, including chart notes from Dr. ML, describing this purported fracture, as well as a CMN, and a prescription bearing Dr. ML's signature. But Dr. ML did not order a Physio-Stim bone growth stimulator for this patient. RIGSBY falsified the chart notes, CMN and prescription to induce Medicare to pay this claim. Medicare paid Orthofix \$3,289.50 for this claim.

RIGSBY Falsified Medical Records to Induce Medicare to Pay Unauthorized Claims

- 23. Between 2005 and 2009, numerous physicians in **RIGSBY's** territory prescribed bone growth stimulators for patients where the claim did not satisfy the insurance carrier's guidelines for reimbursement. When this occurred, **RIGSBY** frequently falsified patient medical records and forged physicians' signatures on prescriptions and CMNs to make it appear as though the orders met these guidelines to induce the insurance carrier to pay the claims.
- 24. For example, in November 2008, Dr. CT performed a triple arthrodesis fusion surgery on the left foot of patient DS. In April 2009, Dr. CT prescribed a bone growth stimulator

for patient DS. Medicare would not have paid for this claim because nine months had not elapsed since the fusion surgery.

- 25. **RIGSBY** submitted a fraudulent claim to Orthofix for a bone growth stimulator for patient DS. In two separate chart notes, **RIGSBY** deleted Dr. CT's description of the left triple arthrodesis procedure and Dr. CT's assessment that the injury was partially healed. Instead, **RIGSBY** falsely wrote that DS had a "left 5th metatarsal fracture" and that "[t]his appears to be a nonunion." **RIGSBY** falsified patient DS's medical records to make it appear as though DS had a nonunion in the 5th metatarsal bone—which would support a Medicare claim for a bone growth stimulator. **RIGSBY** also falsified the CMN that was purportedly completed by Dr. CT.

 Medicare paid Orthofix \$3,289.50 and a secondary insurer paid \$822.37 for this claim.
- 26. As another example, in March 2009, Dr. SS performed spinal fusion surgery on patient PC. Dr. SS performed a "L4-L5 spondyloslisthesis with spinal stenosis and lateral recess syndrome." Medicare would not have paid this claim because Dr. SS performed a spinal fusion of only two vertebrae (L4-L5) ("single-level fusion"), and Medicare only pays for spinal fusions of three or more vertebrae ("multi-level fusions").
- 27. **RIGSBY** submitted a claim to Orthofix for a bone growth stimulator for patient PC. **RIGSBY** falsified Dr. SS's chart notes related to patient PC. **RIGSBY** forged the operation note to state that Dr. SS performed a "L4-S1 spondylolisthesis . . ." **RIGSBY** falsified this note to make it appear as though Dr. SS performed a multi-level fusion, which is payable by Medicare, when in fact, Dr. SS performed a single-level fusion, which is not covered by the Medicare Program. In addition, **RIGSBY** forged Dr. SS's signature on the prescription accompanying the claim. Medicare paid Orthofix \$3,268.19 for this claim.

Orthofix Terminates RIGSBY

- 28. In July 2008, **RIGSBY** submitted a fraudulent order for a Physio-Stim for patient JD. Patient JD had suffered a fracture of the pelvis, and Dr. WO prescribed a bone growth stimulator. Medicare would not have paid this claim because (1) injuries to pelvic bones are not payable under Medicare Program guidelines; and (2) Dr. WO indicated in patient JD's medical records that the injury was healing, which would have precluded payment.
- 29. **RIGSBY** falsified Dr. WO's chart notes related to patient JD, deleting the reference to a pelvic fracture and writing that JD had a "proximal femur fracture," which could be payable under Medicare Program guidelines. **RIGSBY** also deleted Dr. WO's statement that the injury was healing, writing instead that "X-rays show no evidence of callus formation" and that JD had a "nonunion." **RIGSBY** also postdated the date of the patient visit. **RIGSBY** falsified this order to make it appear as though patient JD had a nonunion of a femur fracture that had not healed for 90 days—an injury that would support a claim for a bone growth stimulator.
- 30. Orthofix personnel determined that **RIGSBY** had falsified this order. **RIGSBY** falsely denied any wrongdoing. **RIGSBY** went so far as to cause one of Dr. WO's employees to fax the falsified records from Dr. WO's office and falsely state in the fax cover page that the falsified records "are in the pt. chart."
 - 31. On July 9, 2009, Orthofix terminated **RIGSBY** for falsifying the JD order.

The Peg Medical Scheme

32. Orthofix sales personnel, including **RIGSBY**'s former managers Mitch Salzman and Tom Guerrieri, were concerned that, without **RIGSBY**, Orthofix would lose business in the Knoxville, TN area. Thus, Orthofix sales personnel and **RIGSBY** concocted a scheme in which

Orthofix would continue to pay **RIGSBY** to obtain bone growth stimulator orders in his former territory, but he would submit the orders through a shell company, concealing his identity.

- 33. In August, 2009, **RIGSBY** incorporated a company called Peg Medical, Inc. ("Peg Medical"). Between August 2009 and December 2010, Orthofix entered into various arrangements with **RIGSBY** through Peg Medical, paying commissions to Peg Medical for stimulator orders. In December 2010, Orthofix hired Peg Medical to be the exclusive distributor of the Cervical-Stim and Spinal-Stim in the Knoxville territory.
- 34. **RIGSBY** took numerous steps to conceal his affiliation with Peg Medical. For instance, in the Peg Medical charter, **RIGSBY** concealed his name and identified JB, one of his closest childhood friends, as the registered agent for Peg Medical. **RIGSBY** paid JB to represent himself as the principal of Peg Medical. JB signed several contracts with Orthofix on Peg Medical's behalf, even though JB—a construction worker by trade who had no experience in medical sales—performed no substantive work for Peg Medical. In addition, **RIGSBY** was careful not to communicate on email with Orthofix personnel through an account bearing his name. Instead, **RIGSBY** communicated with Orthofix personnel and others using the email address <u>PegMedical@yahoo.com</u>. **RIGSBY** also changed the identifier on his fax machine to a series of zeroes, instead of his name and fax number.
- 35. Orthofix initially hired two territory managers, LJ and JC, to nominally replace Rigsby in selling the spine stimulators and the Physio-Stim respectively. But **RIGSBY** continued to call on physicians and obtain medical records for Orthofix stimulator orders. **RIGSBY** usually provided the medical records to LJ and JC to submit to Orthofix under their names. On some

occasions, however, **RIGSBY** simply faxed the orders to Orthofix himself under the name of LR or JC.

- 36. **RIGSBY** continued to manipulate, falsify and forge medical records even after he was terminated by Orthofix for this conduct. Moreover, **RIGSBY** trained Orthofix territory manager LJ to falsify CMNs and forge prescriptions, telling LJ that LJ would lose business if he required physicians to sign these forms for each order.
- 37. For instance, in October 2009, Dr. PS performed spinal surgery on patient MM. RIGSBY created phony chart notes under the name of Dr. WO—not Dr. PS—indicating that patient MM had a right ankle fracture. In fact, Dr. WO never saw this patient, patient MM had a spinal injury, not an ankle injury, and a physician did not order a stimulator of any kind for MM. RIGSBY submitted this claim to Orthofix under JC's name. Medicare paid Orthofix \$3,700.69 for this claim.
- 38. As another example, in August 2010 **RIGSBY** submitted, through JC, an order for a Physio-Stim for patient RS. **RIGSBY** created phony medical records indicating that Doctor TP treated patient RS for a fractured toe, and that Doctor TP ordered a Physio-Stim for this patient. In fact, Doctor TP never saw this patient, RS did not have this injury, and RS never received a Physio-Stim. Medicare initially paid \$4,111.87 for this claim, but after the patient's family complained to Medicare, Orthofix repaid the claim.

Loss to Federal Programs Due to RIGSBY's Scheme

39. Between 2005 and 2011, Medicare and other federal insurance carriers paid Orthofix more than \$400,000 for Physio-Stim bone growth stimulators where **RIGSBY** falsified medical records to meet insurance guidelines for payment.

All in violation of 18 U.S.C. \S 1347 and 18 U.S.C. $\S 2.$

COUNT 2 42 U.S.C. §1320A-7b (KICKBACKS)

- 40. The allegations set forth in paragraphs one through 16 are herein realleged and incorporated in full.
 - 41. In or about 2010 or 2011, in the Eastern District of Tennessee, the defendant

HUNTER RIGSBY,

did knowingly and willfully offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to NS and BH to induce NS and BH to purchase, lease, order, and arrange for, and recommend purchasing, leasing, and ordering goods, items and services, for which payment was made or might have been made in whole and in part by Medicare, a federal health care program, in violation of 42 U.S.C. § 1320a-7b(b)(2)(B) and 18 U.S.C. § 2, as set forth below.

The NS Kickback

- 42. NS was an employee at one of the largest physicians' practices in Tennessee. NS was responsible for ordering bone growth stimulators prescribed by physicians. Often the physician did not specify which brand of stimulator he or she preferred. In those situations, NS was in a position to direct the stimulator business to the manufacturer of his choice.
- 43. Fully aware of NS's role, **RIGSBY** approached NS and asked if he could pay NS for bone growth stimulators. NS agreed to this arrangement. A few days later, **RIGSBY** called and asked for NS's address, which NS provided. That night, when NS returned home, NS found an envelope on NS's doorstep with \$200 in cash inside. NS's name was written on the front of the envelope.

44. **RIGSBY** made the \$200 cash payment to thank NS for directing stimulator orders to Orthofix in the past and to induce NS to continue to choose Orthofix when physicians prescribed stimulators in the future.

The BH Kickback

- 45. BH was a registered nurse who worked for Dr. NG, a surgeon in Morristown, TN.
- 46. In approximately the summer of 2011, **RIGSBY**, BH and Dr. NG agreed that **RIGSBY** would pay BH for each stimulator ordered by Dr. NG. The purpose of the arrangement was to induce BH and Dr. NG to order Orthofix stimulators.
- 47. In approximately September 2011, **RIGSBY** contacted BH and instructed BH to look in the back of BH's truck. BH found an envelope in a console in the back of BH's truck. The envelope contained between \$200 and \$300 in cash. This money represented payment for Orthofix stimulators ordered by BH and Dr. NG.

All in violation of 42 U.S.C. §1320A-7b and 18 U.S.C. §2

FORFEITURE ALLEGATION (18 U.S.C. § 982)

- 48. The allegations set forth in paragraphs 1 through 47 are herein incorporated in full.
- 49. Upon conviction of one or more of the offenses alleged in Counts One and Two of this Information, the defendant,

HUNTER RIGSBY

shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses. Such property includes, without limitation, the following:

- a. a sum of money equal to \$70,000 in United States currency, representing the amount of gross proceeds traceable to the offenses.
- 50. If any of the property described in paragraph 49 above, as a result of any act or omission of the defendant
 - a. cannot be located upon the exercise of due diligence;
 - b. has been transferred or sold to, or deposited with, a third party;
 - c. has been placed beyond the jurisdiction of this Court;
 - d. has been substantially diminished in value; or
 - e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to 18 U.S.C. § 982(b)(1), incorporating 21 U.S.C. § 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in paragraph 49 above.

All pursuant to Title 18, United States Code, Section 982(a)(7).

CARMEN M. ORTIZ United States Attorney

By:

DAVID S. SCHUMACHER Assistant U.S. Attorney